Glossary of Terms

- **2D plus 3D images** – a set of images that allow radiology is compare the results of a standard 2D mammogram image and the corresponding 3D tomosynthesis image, while viewing them independently at the same time
- **3D** – Tomosynthesis 3D images
- **$3D_S$** – Tomosynthesis 3D images plus Synthesized 2D images
- **Acquisition Study** – a clinical study where the main purpose is to acquire a large and diverse number of images from a number of different locations, with the intention of using the images later on in reader studies
- **ACR Breast Phantom** – American College of Radiology Breast Phantom – simulated breast material containing masses, fibers and specs, that is used to assess image quality
- **Architectural Distortion** – when the breast tissue has changed in shape or structure, or identification of spicules without an associated mass. It may be due to scarring from previous surgery, radial scars (benign breast lesions) or carcinoma (cancer)
- **Asymmetry** – a difference in the size or shape of the breast
- **Average Glandular Dose** – the average amount of radiation breast tissue is exposed to, taking into account the breast composition and amount of breast compression
- **BEIR VII data** – from the epidemiology paper *Health Risks from Exposure to Low Levels of Ionizing Radiation,* that supports the evidence of cancer occurrence based on exposure to radiation
- **Benign Biopsy Case** – a case that where a biopsy was performed on a suspicious area and the results came back benign
- **Benign Case** –a case finding that is characteristically benign or non-cancerous
- **Bilateral 2-view mammogram** –both breasts were imaged in both CC and MLO views
- **Binary Endpoint** – if the case was either recalled or not recalled
- **BI-RADS score** – Breast Imaging-Reporting and Data System – a standardized numerical code (with values from 0-6) assigned by a radiologist after interpreting a mammogram: 0 – incomplete and needs additional work-ups, 1 – Negative, 2 – Benign finding(s), 3 –Probably Benign, 4 – Suspicious abnormality, 5 – Highly suggestive of Malignancy, 6 – Known Biopsy – Proven Malignancy

- **Bonferroni Adjustment** – a method of altering the level of significance for each measure so that the overall change of at least one significant measurement is 5%
- **Cancer recall rate** – the amount of recalled mammography cases that turned out to be cancerous
- **CC** (Cranio-caudal) **view** - images the breast from above taken of the right (RCC) or left (LCC) breast
- **Compression paddle** – used to compress the breast during a mammogram
- **Conventional 2D images FFDM –**2D images taken during a screening exam, usually by a digital mammography device, and consists of a CC and MLO image of each breast for a set of 4 images (LMLO, LCC, RLMO, RCC)
- **CT Scan** – CAT Scan (computed tomography) – special non- invasive x-ray equipment that produces multiple images of the inside of the body. This provides greater clarity reveals more details than regular x-ray exams. Images are viewed on a computer monitor, printed or transferred to a CD
- **DBM multi-reader multi-case ROC software** – Statistical software for generating ROC curves based on fixed data points provided by more than one variable (in this case more than one reader and more than one case)
- **Decision Threshold** – as it pertains to this data, it is if the radiologist decided to recall or not recall the case
- **Dense Breast** – BI-RADS density score of 3 or 4
- **Detector housing** – the portion of the device which receives x-ray information once it has passed through the breast. It is then converted into a digital imaged viewed on a monitor by the radiologist
- **Digital Mammography** – a mammography technique that allows the images to be viewed on a computer monitor instead of having to print out the images on x-ray films
- **Enriched Reader Study** –the case set in a reader study is made up of either cancer or recalled cases
- **False positive** – a result that is erroneously positive when a situation is normal
- **FFDM** – Full Field Digital Mammography - a digital mammography system that allows images to be viewed on a computer monitor or printed onto film

- **Forced BIRADs (FB)** – a BI-RADs score of a 1 through 5 (includes 1, 2, 3, 4a, 4b, 4c, 5,) which the readers must give if they had given the case an initial BI-RADs score of zero. This score is based solely on the mammogram images presented to the reader and not the actual results of any additional work-up that may have been performed pertaining to that specific case
- **FPF- False Positive Fraction (non-cancer recall rate)** – the amount of times a non-cancerous case was unnecessarily recalled by the reader
- **Gantry control board** – A part of the system that controls the Detector Generator, and the x-ray source, positioning/compression, Power distribution and subsystems (the Gantry)
- **Ground Truth** – the determination of true cancer identification and location based on the outcome of a biopsy and reported pathology findings
- **Hanging Protocol** – determines how and in what order images appear when viewing a case during the reader study. This is meant to assure consistency when the images are viewed on different workstations by different radiologist
- **Image set** – a total set of 4 images consisting of a CC and MLO image of each breast
- **Initial BI-RADs** – a BI-RADs score of either a 0 (incomplete), 1 (negative) or 2 (benign), used as a preliminary assessment of a case in the reader study
- **Internal breast marker** – a small marker placed inside the breast that is clearly visible on x-ray. It is used to either identify an area that needs to be continuously monitored or an area that had previously been biopsied
- **Lesion or mass** – abnormal tissue that may be cancerous
- **Lesion-based scoring** – radiologist giving the images in the Reader Study a BI-RAD score and a probability of malignancy score based on specific suspicious areas that they had marked on the image via classification of the area and location
- **Mammography Quality Standards Act (MQSA)** – enacted by the United States Congress meant to regulate and quality of care in mammography and requires that mammography facilities across the nation meet uniform quality standards
- **McNemar's Test** – a test for comparing even rates. In this study we are comparing the sensitivities of two diagnostic tools – conventional 2D mammography verse 3D tomosynthesis
- **Microcalcification** – specks of calcium that may be found in an area of rapidly dividing cells and may indicate a small cancer

- **MLO** (Mediolateral Oblique) **view** – is a mammographic image taken from an oblique or angled view taken of the right (RMLO) or left (LMLO) breast. During routine screening mammography, the MLO view is preferred over a lateral 90-degree projection because more of the breast tissue can be imaged in the upper outer quadrant of the breast and the axilla (armpit)
- **Negative Case** – a case where there are no abnormal areas or findings
- **Non-cancer recall rate** – the amount of recalled mammography cases that turned out to be non-cancerous
- **Normal Glandular Tissue** – a cluster of epithelial cells that are involved in the production and transportation of secretions. In the breast this refers to the tissue involved in producing and transporting milk
- **One Bilateral View** – a view (either MLO or CC) taken of both breast
- **Operating Points** – are the plotted sensitivity and specificity points that construct the ROC curve
- **Patient-based scoring** – radiologist giving the images in the Reader Study a BI-RADs score and probability of malignancy score based upon the overall appearance of the breast and the appearance of any suspicious areas
- **Positive Case** – a case that has been identified as having cancer
- **Probability of Malignancy (POM)** – the probability that an abnormal area is cancerous
- **Projection images** – The group of x-ray images for tomosynthesis taken at different projection angles through the breast
- **QC Review** – quality control review
- **Recall Case** – a case where there is a suspicious area(s) identified in the screening exam that need additional work-ups to determine if the area is cancerous or not
- **Receiver Operator Characteristic (ROC)** – A graphical plot of the sensitivity (or true positive) verse (1-specificity), or false positives, or a binary classifier system
- **ROC AUC** – or the ROC Curve corresponds to the area under the ROC Curve with a greater area value being better
- **Scheffe Type Control** – way of limiting the chance of finding a coincidental significant difference when multiple tests are performed, by first comparing all test to see if they are equal (non-significant findings) before performing additional tests to determine significance
- **Screen-film mammography** – a mammography technique where the images are viewed on x-ray films

- **Screening exam** – a standard of care exam, where asymptomatic women receive a full set of mammographic images (CC and MLO of both breasts), with the purpose of detecting any potential areas of concern
- **Screening verse diagnostic use** – screening refers to the standard of care mammogram taken yearly of an asymptomatic patient. Diagnostic means that either a palpable lump has been identified in the breast or a suspicious area has been identified during the screening exam, and it requires additional imaging and work-up to determine if it is cancerous
- **Sensitivity** – or true positive, is when a case has been correctly identified
- **Soft tissue lesion** – an abnormal area of skin or mucosa
- **Spatial Resolution** – how closely lines can be resolved in an image or the clarity of the image
- **Spiculated mass** – a mass or lesion characterized by lines (or spiculations) radiating from the margins of the mass- resembling a sunburst or a wagon wheel
- **Standard of Care (SOC)** – refers to the subject's standard of care clinical imaging, as opposed to the investigational imaging
- **Superimposition of Tissue** – layers of tissue above and below an area of interest, obscuring visualization of the area in question
- **Synthesized 2D** – A 2D image created from the tomosynthesis (3D) images. Requires no additional radiation dose
- **System's acquisition workstation (AWS)** – computer workstation that receives images once the mammogram is complete
- **TPF- True Positive Fraction (Cancer recall rate)** – the amount of times a cancerous case was properly recalled by the reader
- **Type 1 Error** – in statistics when the null hypothesis is inappropriately rejected